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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,539	04/18/2001	John M. Barker	1032-P02148US1	7584

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 06/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/837,539

Applicant(s)

BARKER ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “**240**” as described on page 18, lines 6-8 and 10. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: “**454**” as illustrated in Figures 15 and 16. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to because in Figure 18 the uppermost occurrence of reference sign “**492**” apparently should be deleted. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

5. Claims 1 and 8 are objected to because of the following informalities: in line 6, --;-- apparently should be inserted after "element". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations "the projecting position" in lines 10-11; "the forward edge of the shield" in line 12; and "the retracted position" in lines 12-13. There is insufficient antecedent basis for these limitations in the claim. There is no projecting position or retracted position recited in the claim prior to these recitations. Furthermore, the shield is not disclosed as having a forward edge in the claim prior to this recitation.

Claim 8 recites the limitations "the projecting position" in lines 10-11; "the forward edge of the shield" in line 12; and "the retracted position" in lines 12-13. There is insufficient

antecedent basis for these limitations in the claim. There is no projecting position or retracted position recited in the claim prior to these recitations. Furthermore, the shield is not disclosed as having a forward edge in the claim prior to this recitation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al.

Song et al. teaches a medical device including a hollow housing **3**; a needle **9** having a sharpened tip projecting forwardly from the housing; a biasing element **5** biasing the needle rearwardly; a needle retainer releasably retaining the needle against the rearward bias of the biasing element; and a flexible shield **12** fixedly attached to the housing, projecting forwardly from the housing. The shield is configured for insertion into a patient. The shield sheathes the needle such that in a projecting position the sharpened tip of the needle projects beyond the forward edge of the shield, and in a retracted position the sharpened tip is enclosed within the shield. The shield is substantially puncture resistant so that the axial force required to buckle the shield is less than the force necessary to puncture the shield with the needle in order to prevent inadvertent contact with the contaminated needle.

Song et al. further teach a method for infusing fluid into a patient with a medical device having a needle including the steps of inserting the needle into the patient; displacing the needle

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rearwardly such that the needle is shielded; and infusing fluid through the shielded needle into the patient. The sheath that forms the shield substantially sheathes the length of the needle.

Song et al. teach method for transfusing one of blood and plasma in or out of a patient with a medical device having a needle including the steps of inserting the needle into the patient; displacing the needle rearwardly such that the needle is shielded; and transferring one of blood and plasma through the shielded needle while a portion of the device is inserted in the patient. The sheath that forms the shield substantially sheathes the length of the needle.

Conclusion

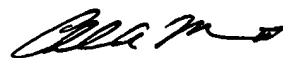
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Halseth et al. teach a medical device for inserting a guide wire having a retractable needle. Lemke et al. teach an IV protector designed to prevent splattering of blood from the tip of a peripheral IV catheter. Arnett teaches a needle protector having a body, a needle hub, and a needle. Hogan teaches a blood collecting apparatus with shielded needles.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Examiner
Art Unit 3736



CAM

June 12, 2002